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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,799	10/03/2001	Karl Andrew Garrill	PG4113US2	3583

23347 7590 05/21/2003

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EXAMINER

FOSTER, JIMMY G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 05/21/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/971,799

Applicant(s)
Garrill et al.

Examiner
Jimmy G. Foster

Art Unit
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-125 is/are pending in the application.
- 4a) Of the above, claim(s) 2, 4-10, 82-88, and 117-123 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 11-28, 30-56, 60, 61, 63-67, 70-81, 89-116, 124, and 125 is/are rejected.
- 7) ☒ Claim(s) 29, 57-59, 62, 68, and 69 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2,3 6) ☐ Other:

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1. Claims 2, 4-10, 82-88 and 117-123 are withdrawn from further consideration as being directed to species non-elected without traverse in paper 5.
2. Applicant is advised that should claim 19 be found allowable, claim 25 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
3. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This application is a continuation of parent application Ser. No. 09/599,746 and therefore must not include *new matter* beyond what is disclosed in said parent application. Claim 56 includes new matter since it calls for one or more desiccants to be impregnated into one or more heat seal layers, which is not disclosed by the parent application.
4. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 72, 78-80, 106-108, 114 and 115 are rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 4-6, 12-14, 18 and 19 respectively of prior U.S. Patent No. 6,179,118. This is a double patenting rejection. Applicant should note that a statutory double patenting rejection cannot be overcome by filing a terminal disclaimer.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 105 is rejected under 35 U.S.C. § 102(b) as being anticipated by Homan (4,645,073). Homan includes a container 16 which holds a drug. The container is enclosed in a moisture impermeable pouch/bag 14.

Into the container a diluent is inserted by syringe. This facilitates mixing of the drug with the diluent. But this also elevates the pressure of the gas which was located in the container. The reference indicates (col. 5, lines 22-33) that upon mixture of the drug and diluent, the container is likely to include the drug in aerosol form, which is a dispersed form and/or dissolved form. The added pressure in the container is likely to propel the aerosol from the container into the pouch 14. Therefore the reference of Homan discloses a pressurized

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drug formulation comprising a propellant and a drug dispersed and/or dissolved in said propellant. The pressurized drug formulation is located within the container to be contained thereby until release by removal of the syringe S from the septum 28 of the container. Inasmuch as Applicant's containing means holds the drug formulation until dispensed, the containment and release is therefore in the same way as it is with Homan. Therefore, the container of Homan is considered as being equivalent to the containing means claimed by Applicant.

8. All examined claims, except for claim 105, distinguish over the prior art.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 3, 11-13, 19, 22-28, 30-43, 53-55, 60, 61, 63-67, 70, 71, and 105 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6, 7, 10, 11, 12, 14, 15, and 16 of U.S. Patent No. 6,315,112.

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Regarding claims 1, 3, 11-13, 19, 22-28, 40, 41, 55, 71, and 105, although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have made the product presently claimed upon making the apparatus as set forth in the patent claims since the patent claims include substantially all of the subject matter set forth in the present claims. In this manner the claims correspond as follows (present claim/patent claim): 1/1, 3/3, 11/3, 12/4, 13/4, 19/1, 22/10, 23/11, 24/12, 25/1, 26/14, 27/15, 28/16, 35/1, 40/10, 41/11, 55/7, 71/1, 105/1.

Claim 35 does not patentably distinguish patent claim 1 since the metallic also constitutes a protective layer. Claims 19 and 25 do not distinguish over patent claim 1 since the abbreviation "HFA" refers to the term "hydrofluoroalkane."

Regarding claims 42 and 43, these claims do not patentably distinguish over patent claim 11 since patentability of a product can not be predicated on its method of being made. The patent claim 11 already calls for an aluminum foil layer. The method of making such a layer would patentably distinguish the presently claimed layer over the one of patent claim 11.

Regarding claims 53 and 54, it is known to make pouch seams by adhesive sealing or by heat sealing of polyolefin or ionomer layers for enclosing contents of the pouch and permitting the pouch to be made of sheet material. And such seals are equivalents in the pouch making art since they both function to attach facing surfaces of pouch walls together so as to form a pocket or enclosure. Accordingly, it would have been obvious to have formed the pouch of patent claim 1 with heat

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sealing or adhesive sealing of seams for the purpose of enclosing the pressurized container by using sheet material.

Regarding claim 70, it is known to use adhesive lamination to form a multilayer sheet material since adhesive allows facing attachment of material layers that can not be combined on their own. Accordingly, for this reason it would have been obvious to have used an adhesive for attachment of the desiccant layer of patent claim 6 to the foil layer.

Claims 30-34, 36-39, 60 and 63-67, which call for specific layer thicknesses, do not further patentably distinguish over patent claim 1 or 11 since it has been held that where the general conditions of a claim are present in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

11. Claims 14-18, 20 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 8, 9 and 17 of U.S. Patent No 6,315,112 in view of published European Patent Application No 0,428,380 to Wass et al. Wass et al suggest that a container for pressurized drug formulation may include a metering valve and an actuator for the purpose of dispensing the drug by actuation. Accordingly, for this reason it would have been obvious to have provided the container of any of the above patent claims with a metering valve and an actuator.

12. Claims 44-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No 6,315,112 in view of

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Lloyd et al (5,522,385). The reference of Lloyd et al suggests that the drug in an aerosolized drug delivery may include excipients in the form of preservatives to apparently preserve the drug formulation, and ethanol to act as a carrier for the active ingredients of the drug. Accordingly for such functions it would have been obvious to have provided preservatives or ethanol to the drug formulation of patent claim 1. Moreover, inasmuch as claim 49 is an alternative claim, the specific recitations of claims 51 and 52, dependent from 49, are considered to be met the teaching of Lloyd et al to provide preservatives, even though claims 51 and 52 call for the co-solvent to be substances not actually disclosed by Lloyd et al.

To have provided any amounts of excipients, such as those amounts claimed by present claims 45-45 would have been further obvious as merely discovering workable ranges for the general condition(s) taught by Lloyd.

13. Claims 73-77, 81, 89, 93, 105, 109-113, 116, 124, and 125 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 5, 7, 12, 18, 20 and 25 of U.S. Patent No. 6,179,118.

Regarding claims 73-76, 81, 89, 93, 105, 113, 116, 124, and 125, although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have made the product presently claimed upon making the apparatus as set forth in the patent claims since the patent claims include substantially all of the subject matter set forth in the present claims. In this manner the

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claims correspond as follows (present claim/patent claim):

73/2, 74/3, 75/2, 76/3, 81/7, 89/7, 93/5, 105/25, 113/18,
116/20, 124/20 and 125/12.

Regarding claim 109-112, which call for the providing the desiccant in a sachet, it is known to do this for the purpose of keeping the desiccant from becoming mixed with the contents of a package. To have further have provided the desiccant of patent claims 15 and 16 in a sachet would have been obvious for this reason.

Regarding claim 77 and 111, which further call for a particular amount of silica gel, this claims does not patentably distinguish over the silica gel claimed (the general condition) in claim 3, which is used as a moisture absorbent since it has been held that where the general conditions of a claim are present in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

14. Claims 90-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No 6,197,118 in view of published European Patent Application No 0,428,380 to Wass et al. Wass et al suggest that a container for pressurized drug formulation may include a metering valve and an actuator for the purpose of dispensing the drug by actuation. Accordingly, for this reason it would have been obvious to have provided the container of any of the above patent claims with a metering valve and an actuator.

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15. Claim 94 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No 6,197,118 in view of Schirmer (4,815,602). The reference of Schirmer suggests that vacuum sealing the flexible material of an outer container about a content will result in the outer container conforming in a tight-fitting manner about the content. Accordingly, it would have been obvious in view of Schirmer to have vacuum sealed the outer pouch of patent claim 1 about the drug container for the purpose of achieving a tight-fitting conformance with respect to the container.

16. Claim 95 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No 6,197,118 in view of Halskov (4,664,256). Halskov suggests providing nitrogen in the outer package which encloses a drug in a drug delivery container, for the purpose of preventing oxidation or destabilization of the drug contained. Accordingly, it would have been obvious in view of Halskov to have provided nitrogen gas in the pouch of patent claim 1.

17. Claims 96-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No 6,197,118 in view of Lloyd et al (5,522,385). The reference of Lloyd et al suggests that the drug in an aerosolized drug delivery may include excipients in the form of preservatives to apparently preserve the drug formulation, and ethanol to act as a carrier for the

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active ingredients of the drug. Accordingly for such functions it would have been obvious to have provided preservatives or ethanol to the drug formulation of patent claim 1. Moreover, inasmuch as claim 101 is an alternative claim, the specific recitations of claims 103 and 104, dependent from 101, are considered to be met the teaching of Lloyd et al to provide preservatives, even though claims 103 and 104 call for the co-solvent to be substances not actually disclosed by Lloyd et al.

To have provided any amounts of excipients, such as those amounts claimed by present claims 97-100 would have been further obvious as merely discovering workable ranges for the general condition(s) taught by Lloyd.

18. Claims 72-80, 90-93, 105-115 and 125 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 5, 7, 12, 18, 20 and 25 of U.S. Patent No. 6,119,853.

Regarding claims 73-76, 80, 90-93, 105-108, 113-115 and 125, although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have made the product presently claimed upon making the apparatus as set forth in the patent claims since the patent claims include substantially all of the subject matter set forth in the present claims. In this manner the claims correspond as follows (present claim/patent claim): 72/1, 73/3, 74/4, 75/2, 76/4, 78/3, 79/9, 80/9, 90/21, 91/21, 92/21, 93/9, 105/1, 106/1, 107/22, 108/23, 113/9, 114/10, 115/10 and 125/1.

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Regarding claim 109-112, which call for the providing the desiccant in a sachet, it is known to do this for the purpose of keeping the desiccant from becoming mixed with the contents of a package. To have further have provided the desiccant of patent claims 15 and 16 in a sachet would have been obvious for this reason.

Regarding claim 77 and 111, which further call for a particular amount of silica gel, this claims does not patentably distinguish over the silica gel claimed (the general condition) in claim 3, which is used as a moisture absorbent since it has been held that where the general conditions of a claim are present in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

19. Claim 94 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No 6,119,853 in view of Schirmer (4,815,602). The reference of Schirmer suggests that vacuum sealing the flexible material of an outer container about a content will result in the outer container conforming in a tight-fitting manner about the content. Accordingly, it would have been obvious in view of Schirmer to have vacuum sealed the outer pouch of patent claim 1 about the drug container for the purpose of achieving a tight-fitting conformance with respect to the container.

20. Claim 95 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claims 1 of U.S. Patent No 6,119,853 in view of Halskov (4,664,256). Halskov suggests providing nitrogen in the outer package which encloses a drug in a drug delivery container, for the purpose of preventing oxidation or destabilization of the drug contained. Accordingly, it would have been obvious in view of Halskov to have provided nitrogen gas in the pouch of patent claim 1.

21. Claims 96-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No 6,119,853 in view of Lloyd et al (5,522,385). The reference of Lloyd et al suggests that the drug in an aerosolized drug delivery may include excipients in the form of preservatives to apparently preserve the drug formulation, and ethanol to act as a carrier for the active ingredients of the drug. Accordingly for such functions it would have been obvious to have provided preservatives or ethanol to the drug formulation of patent claim 1. Moreover, inasmuch as claim 101 is an alternative claim, the specific recitations of claims 103 and 104, dependent from 101, are considered to be met the teaching of Lloyd et al to provide preservatives, even though claims 103 and 104 call for the co-solvent to be substances not actually disclosed by Lloyd et al.

To have provided any amounts of excipients, such as those amounts claimed by present claims 97-100 would have been further obvious as merely discovering workable ranges for the general condition(s) taught by Lloyd.

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22. Claim 105 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 6,390,291.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have made the product presently claimed upon making the apparatus as set forth in the patent claim since the patent claim includes substantially all of the subject matter set forth in the present claim.

23. Claim 105 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/071,674. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have made the product presently claimed upon making the apparatus as set forth in the patent claim since the patent claim includes substantially all of the subject matter set forth in the present claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claim 105 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/599,274. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have made the product presently

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claimed upon making the apparatus as set forth in the patent claim since the patent claim includes substantially all of the subject matter set forth in the present claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 29, 57-59, 62, 68 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

26. For contacting the PTO by phone, the following contact numbers may be used:

For tracking of papers and association of papers with cases --
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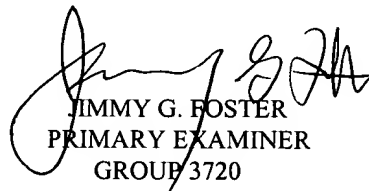
For matters regarding examination -- Examiner:
Jim Foster (703)308-1505

For faxing of correspondence:
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For petitions:
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Before the Group Director . (703)308-3872
Other petitions . . . (703)305-9282


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